GENERAL PHARMACY SERVICE REQUIREMENTS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes guidelines for areas of pharmacy practice not covered in other policies, providing comprehensive pharmacy services and oversight by Veterans Integrated Service Networks to ensure safe and efficient medical facility pharmacy operations.

2. SUMMARY OF CONTENT:

a. **Amendment, dated December 6, 2024, updates:**

(1) Licensure requirement for Pharmacy residents in paragraph 6.

(2) Medication storage compliance requirements in paragraph 9.

(3) Medication safety and verbal or telephone medication order practices in paragraph 10.

(4) Criteria for reviewing medication orders in paragraph 12.

(5) Practice for providing low-cost drugs to treat chronic conditions in paragraph 13.

(6) Timelines, language, and preceptor eligibility in Appendix A.

(7) Prescribing practices in Appendix C.

b. **Amendment, dated October 4, 2023**, updates language in Appendix A.

c. **As published November 28, 2022,** this is directive updated and streamlined policy for VHA pharmacy practice and pharmacy services to Veterans.

3. RELATED ISSUES: VA Handbook 0730, Security and Law Enforcement, dated August 11, 2000; VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020; VHA Directive 1108.01(1), Controlled Substances Management, dated May 1, 2019; VHA Directive 1108.02(2), Inspected of Controlled Substances, dated November 28, 2016; VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022; VHA Directive 1108.12, Management and Monitoring of Pharmaceutical Compounded Sterile Preparations, dated November 5, 2018; VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 27, 2023; VHA Directive 1660.01, Health Care Resources Sharing Authority-Selling, dated June 13, 2023; VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020; VHA Directive 7707, VHA Green Environmental Management System and Governing Environmental Policy, dated April 1, 2021; VHA Handbook 1108.04, Investigational

Drugs and Supplies, dated February 29, 2012; VHA Handbook 1108.11(3), Clinical Pharmacy Services, dated July 1, 2015; and VHA Handbook 1400.04, Supervision of Associated Health Trainees, dated March 19, 2015.

4. LOCAL DOCUMENT REQUIREMENT: Appendix F requires that VA medical facilities must have a local medical center policy on medication and vaccine refrigerator and freezer program management (see Appendix F, paragraph 1).

5. RESPONSIBLE OFFICE: The Office of Patient Care Services, Pharmacy Benefits Management Services (12PBM), is responsible for the contents of this directive and for oversight of this directive at the Consolidated Mail Outpatient Pharmacies. Questions may be addressed to the Chief Consultant at 202-461-7360.

6. RESCISSIONS: VHA Handbook 1108.05(2), Outpatient Pharmacy Services, dated June 16, 2016; VHA Handbook 1108.09(2), Pharmacy Education and Training, dated June 24, 2016; VHA Directive 1108.03, Self-Medication Program (SMP), dated November 28, 2016; VHA Directive 1108.06(2), Inpatient Services, dated February 8, 2017; and VHA Directive 1108.07(1), Pharmacy General Requirements, dated March 10, 2017.

7. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of November 30, 2027. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ M. Christopher Saslo
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Assistant Under Secretary for Health
For Patient Care Services/CNO

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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GENERAL PHARMACY SERVICE REQUIREMENTS

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes oversight responsibilities for the management of the Department of Veterans Affairs (VA) pharmacy services. This directive identifies the minimum requirements for VA pharmacy services, not covered in other policies to ensure both consistency of care throughout VA and the continued advancement of VA pharmacy as an industry leader. **AUTHORITY:** Title 38 U.S.C. § 7301(b).

2. BACKGROUND

a. The Pharmacy Benefits Management (PBM) Service, as an essential component of the health care delivery team in VA, is charged with developing standards for the provision of patient-centered pharmacy services by VA Medical Facilities. The services described include (but are not limited to): procurement, storage, security, inventory management, inpatient and outpatient medication distribution, medication safety, Consolidated Mail Outpatient Pharmacy (CMOP), and pharmacy residency training programs.

b. Medical facility Pharmacy services must comply with relevant provisions of 21 C.F.R., including Part 1300 and relevant accreditation standards and regulatory requirements.

3. DEFINITIONS

a. **Authorized Prescriber**. An authorized prescriber ("prescriber") is a provider authorized by law or VA policy to prescribe medications in accordance with their facility approved privileges or scope of practice. This includes physician, dentist, certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified nurse midwife (CNM), certified registered nurse anesthetist (CRNA), physician assistant (PA) or clinical pharmacist practitioner (CPP) that are granted prescriptive authority for medications. Prescriptions for medications may only be written by authorized prescribers.

b. **Clinical Pharmacist.** Clinical Pharmacist is the full performance level pharmacist position. All pharmacists are considered clinical pharmacists, and for purposes of this directive the term clinical pharmacist is used to encompass all pharmacist positions described in VA Handbook 5005/55, Part II/ Appendix G15, Licensed Pharmacist Qualification Standard GS-660, dated June 7, 2012. The role of each clinical pharmacist may differ based on their assignment and must be delineated in their functional statement or scope of practice as appropriate.

c. **Clinical Pharmacist Practitioner.** A clinical pharmacist practitioner (CPP) is a clinical pharmacist with a scope of practice authorized by the medical staff as an Advanced Practice Provider (APP) defined within medical staff bylaws. The CPP provides direct patient care and functions at the highest level of clinical practice, working with a high level of autonomy and independent decision-making within the

parameters of their scope of practice, as defined by the individual medical facility, and performs functions as described in VHA Handbook 1108.11 Clinical Pharmacy Services. For purposes of this directive, the term CPP is assigned to any pharmacist with a scope of practice regardless of their title assignment as outlined in VA's Licensed Pharmacist Qualification Standard, VA Handbook 5005, Staffing, Part II, Appendix II G15, dated June 7, 2019.

d. **Continuous Readiness.** Continuous readiness is proactively maintaining a safe health care environment conducive to high-quality patient care.

e. **Electronic Health Record.** Electronic health record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. ***NOTE:*** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

f. **Environmental Protection Agency Hazardous Waste.** An Environmental Protection Agency (EPA) hazardous waste has the same meaning as a solid waste, as defined in 40 C.F.R. 261.2, and exhibits one or more characteristics identified in 40 C.F.R. part 261, subpart C or is listed in part 261, subpart D, available here: https://www.ecfr.gov/cgi-bin/text-idx?SID=c64ed0ad8dd3e260183bd8430f219c77&mc=true&node=pt40.28.261&rgn=div5#sp40.28.261.d.

g. **EPA Hazardous Waste Pharmaceutical.** An EPA Hazardous Waste Pharmaceutical is a pharmaceutical that is a solid waste, as defined in 40 C.F.R. 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in 40 C.F.R. 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used or reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement or homeopathic drug is not a solid waste, as defined in 40 C.F.R. 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used or reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

h. **Hazardous Drug.** Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and structure and toxicity that mimics existing drugs determined hazardous by the above criteria.

i. **Health Professions Trainee.** Health Professions Trainee (HPT) is an individual appointed under 38 U.S.C. §§ 7405 or 7406 who is participating in clinical or research training under supervision to satisfy program or degree requirements. HPT is a general

term to describe undergraduate, graduate and continuing education students; interns, residents, fellows and VA advanced fellows; and pre-and post-doctoral fellows who spend all or part of their clinical training experiences at VA medical facilities. For the purposes of this directive, HPT refers to Pharmacy Fellows, Pharmacy Residents and Pharmacy Student Trainees.

j. **Medication Management System.** Medication Management System is the process for handling medications throughout the VA medical facility including procurement, receipt, security, storage, distribution and final disposition.

k. **Non-Medication.** Non-medication refers to products such as oral nutritional supplementation, expendable supplies, wound care and ostomy products that would not be defined as a drug per the Food and Drug Administration (FDA).

l. **Pharmacy and Therapeutics Committee**. For the purposes of this directive, the VA medical facility pharmacy and therapeutics (P&T) committee is composed of actively participating physicians, other prescribers, pharmacists, nurses, administrators, quality-improvement managers and other health care professionals and staff who participate in the medication-use process. The P&T committee is meant to serve in an evaluative, educational and advisory capacity to the medical staff and organizational administration in all matters that pertain to the use of medications.

m. **Scope of Practice.** For purposes of this directive, a scope of practice is a collaborating agreement between the VA medical facility Executive Committee of the Medical Staff (ECMS) or equivalent and CPPs whereby CPPs are permitted to perform comprehensive medication management services. The scope of practice permits autonomy and independent decision-making when performing the authorized duties. The scope of practice may authorize CPPs to dispense, prescribe and administer controlled substances when they are authorized by their State license and they comply with the limitations and restrictions on that authority.

n. **Unit-Dose Drug.** Unit-Dose drugs are medications contained in single unit packages and dispensed in ready-to-administer forms.

4. POLICY

It is VHA policy to provide comprehensive, collaborative and patient-centered services to Veterans for the areas of pharmacy practice and pharmacy services covered by this policy at VA medical facilities.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Ensuring VISN Network Directors comply with this directive, relevant standards and applicable regulations.

c. **Assistant Under Secretary for Health for Patient Care Services.** The Assistant Under Secretary for Health for Patient Care Services is responsible for supporting the Assistant Under Secretary for Health for Operations' implementation and oversight of this directive across VHA.

d. **Chief Consultant, Pharmacy Benefits Management Services.** The Chief Consultant, PBM is responsible for:

(1) Serving as an advisor to the Under Secretary for Health, VA Central Office (VACO) program offices, other governmental agencies, VISNs and VA medical facilities on issues related to standards for pharmacy practice.

(2) Defining policy and guidance regarding pharmacy services to VISNs and VA medical facilities.

(3) Ensuring PBM subject matter experts with a focus on pharmacy services are available to VISNs and VA medical facilities to facilitate continuous readiness and to consult on compliance.

(4) Ensuring the PBM National Educational Needs Assessment (e.g., Pharmacy Workforce Assessment) is performed for all pharmacy staff.

e. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Ensuring all VA medical facilities within the VISN comply with this directive and appendices, accreditation standards and regulations pertaining to pharmacy services, including medication storage.

(2) Ensuring the VISN Pharmacist Executive has authority to provide recommendations related to CPP and professional practice and a role in overseeing the CPP's professional practice evaluation process for VISN-level CPP positions.

(3) Using the VHA Issue Brief process established by the Assistant Under Secretary for Health for Operations, ensuring the reporting of issues through the chain of command that impact the ability for VA medical facilities in the network to provide safe and efficient facility pharmacy operations (e.g., backlog of pending outpatient prescriptions, medication storage or security issues).

(4) Providing resources for the VISN Pharmacist Executive (VPE) and designees to conduct at least one site visit at each VA medical facility pharmacy annually to assess continuous readiness and compliance with pharmacy operational requirements.

(5) Ensuring the VPE develops action plans to address recommendations identified by the Office of the Inspector General, the Office of the Medical Inspector, the Government Accountability Office, other pharmacy operations oversight groups.

f. **Veterans Integrated Services Network Pharmacist Executive.** The VPE is responsible for:

(1) Assisting VISN VA medical facilities with compliance in the areas of pharmacy practice defined in this policy, including but not limited to:

(a) Medication procurement, security, storage, distribution/dispensing, inventory management and disposal.

(b) Compliance with regulations, accreditation requirements and all VA policies to promote an environment of continuous readiness.

(c) Pharmacy education and training which is a joint responsibility of the Office of Academic Affiliations, the VISN Academic Affiliations Office and the VA Medical Facility Associate Chief of Staff for Education/Designated Education Officer as outlined in VHA Handbook 1400.03, dated February 16, 2016.

(2) Providing oversight of the professional practice for all clinical pharmacists and CPPs with VISN-level positions, regardless of the organizational reporting structure of the CPPs or service. This includes hiring, competency assessment, functional statements, DPC responsibilities, recommendations for appointment and scope of practice, or privileges and PPE.

(3) Coordinating communication and required actions between VA medical facilities and VHA Central Office for pharmacy practice.

(4) Conducting at least one quality assurance site visit, in person or virtually, at each VA medical facility pharmacy annually to assess continuous readiness and compliance with pharmacy requirements and ensuring that the quality assurance site visit recommendations are communicated to the VA medical facility and VISN director with defined milestones and target dates.

(5) Ensuring facility action plans are developed and acted upon to address recommendations identified by the Government Accountability Office, Office of the Inspector General, Office of the Medical Inspector and other internal or external pharmacy operations oversight groups.

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and taking appropriate corrective action for non-compliance.

(2) Using the Issue Brief process established by the Assistant Under Secretary for Health for Operations, ensuring the reporting of issues that impact the ability to provide safe and efficient facility pharmacy operations (e.g., backlog of pending outpatient prescriptions, medication storage or security issues).

(3) Providing status updates on the milestones and target dates to the VPE until recommendations identified by the Government Accountability Office, Office of the Inspector General, Office of the Medical Inspector, and other pharmacy operations oversight groups are fully implemented by the target dates. ***NOTE:*** *If the timeline to implement the recommendations needs to be extended, the VA medical facility director shall submit a corrective action plan to the VPE. The corrective action plan requires approval by the network director.*

(4) Ensuring all findings identified in annual VA Security and Law Enforcement review of the Pharmacy Service are corrected.

(5) Ensuring the medical facility Chief, Pharmacy Service is a licensed pharmacist and that the medical facility Chief, Pharmacy Service and Associate Chief, Pharmacy Service positions are at the appropriate grade level as referenced in VA Handbook 5005/55, Part II, Appendix G15, "Licensed Pharmacist Qualification Standard GS-660," dated June 7, 2012.

(6) Ensuring a process for once monthly supervisory review of access to medication storage areas is in place. (e.g. Chief of Pharmacy for pharmacy areas, Nursing for unit, clinic or procedure areas) ***NOTE:*** *Access must be removed as part of the facility employee separation or clearance process.*

(7) Ensuring there is a minimum of one full time VA medical facility Associate Chief, Pharmacy Service who can act on behalf of the VA medical facility Chief, Pharmacy in their absence or if the position is vacant. Additional Associate Chiefs of Pharmacy and supervisory staff will be needed based on pharmacy program complexity. This provides continuous provision of diverse pharmacy services, oversight of a significant percentage of the VA medical facility's budget and promotes succession planning.

(8) Providing adequate staff, space, equipment, fixtures, and other resources to allow pharmacy services to maintain operational, clinical, research and educational responsibilities.

(9) Ensuring that Standard Operating Procedures (SOPs) are developed to address the transportation and provision of medication to patients in a home health setting if the VA medical facility participates in that program. ***NOTE:*** *The P&T Committee must approve non patient specific medications that can be transported and administered to a patient in their home.*

(10) Ensuring all funding for fees associated with the ASHP Residency Accreditation and review process are made available and paid.

(11) Pursuing Veterans Equitable Resource Allocation (VERA) dollars to fund VA medical facility residency programs. ***NOTE****: Sites receive specific dollars for each resident trained. These dollars are to be utilized to run residency programs and includes things such as support staff, travel and lodging to conferences, textbooks and computers.*

(12) Ensuring the Chief of Pharmacy addresses any recommendations identified by the U.S. Government Accountability Office, Office of the Inspector General, VA Office of the Inspector General, and other external and internal pharmacy operations oversight groups.

(13) Ensuring an Issue Brief is submitted in accordance with the processes defined by the Assistant Under Secretary for Health for Operations when the local pending prescription file has greater than 25 prescriptions more than 7 days old for 4 consecutive weeks. The report must include an action plan with a timeline for resolution. ***NOTE:*** *In addition to submitting an Issue Brief, the report and action plan must be provided to the VPE and the Chief Consultant, PBM.*

(14) Ensuring an Associate Chief, Pharmacy Services position is included in the Pharmacy Service's organizational chart regardless of facility complexity. ***NOTE:*** *All staffing requirements noted in this policy must be included in the Pharmacy Service organizational chart.*

h. **VA Medical Facility Chief, Pharmacy Services.** The VA medical facility Chief, Pharmacy Services is responsible for:

(1) Ensuring implementation of all pharmacy requirements in this directive, including all appendixes, to promote safe and efficient foundational pharmacy services which encompass a medication management system, patient-centered customer service and an environment of continuous readiness.

(2) Ensuring the security of pharmacy and other medication storage areas, including a monthly review of appropriate access to pharmacy space. ***NOTE:*** *For further details, see paragraph 8.*

(3) Approving all medication storage areas throughout the facility, including inpatient care areas and clinics. ***NOTE:*** *For further details, see paragraph 9,*

(4) Collaborating with VA medical facility leadership to ensure findings from the Annual Physical Security Review for Pharmacy Services are resolved.

(5) Serving as the VA medical facility subject matter expert on all pharmacy related matters including:

(a) Creating business plans for space, staffing, education, funding and other resources needed to support pharmacy services.

(b) Developing a continuous improvement process with ongoing evaluation.

(6) Implementing high reliability organization principles to promote an empowered and engaged pharmacy workforce, including:

(a) Developing and maintaining pharmacy staff competencies to perform assigned duties.

(b) Ensuring VA medical facility pharmacy services participate in the PBM National Educational Needs Assessment (e.g., Pharmacy Workforce Assessment) for all pharmacy staff.

(c) Ensuring time is available for pharmacy personnel to meet mandatory training requirements.

(7) If the VA medical facility has a pharmacy residency program, ensuring the designation of a VA medical facility Residency Program Director (RPD) who meets established ASHP standards outlined in Appendix A. ***NOTE:*** *The RPD must have time available to devote to necessary educational and training activities on an ongoing basis. In order to successfully implement and maintain an accredited pharmacy residency program, sufficient time must be allocated for program administration. Dedicated time will vary with the number of residents in the program and throughout the year but it should align with OAA Guidance on Protected Educational Time for VA Clinicians available at: https://dvagov.sharepoint.com/sites/VHAOAA/general/Public%20Document/Forms/AllItems.aspx?viewpath=%2Fsites%2FVHAOAA%2Fgeneral%2FPublic%20Document%2FForms%2FAllItems.aspx. This is an internal VA website that is not available to the public.*

(8) Ensuring compliance with VA fiscal, procurement, and inventory requirements (See Appendix B).

(9) Ensuring resolution of prescriptions cancelled back by CMOP and communication to CMOP if changes in pharmaceutical demand occur in a timely manner.

(10) Development of action plans to address recommendations identified by the Office of the Inspector General, the Government Accountability Office, Medical Inspector and other pharmacy operations external and internal oversight groups.

6. LICENSURE AND REGISTRATION REQUIREMENTS

a. All pharmacists' licenses must be current, active and readily available.

b. Pharmacy Technician licenses or certifications must be current, active and readily available.

c. Pharmacy Residents should obtain licensure within --120 days of starting the PGY1 residency training program.

d. It is the pharmacist's responsibility, whether seeking employment or already employed by VA, to immediately inform the VA medical facility Chief, Pharmacy Services and the VA medical facility Chief, Human Resource Management Service if their license has been suspended, revoked or restricted in any way.

e. VA medical facility pharmacies must not register with a State Board of Pharmacy. If a VA medical facility pharmacy is registered with a State Board of Pharmacy, they should discuss with their VISN Pharmacist Executive and develop a plan to revoke or allow registration to expire.

7. SPACE AND STAFFING REQUIREMENTS

a. **Space Requirements.**

(1) Pharmacy spaces, including temperature and humidity, must be maintained in compliance with Office of Construction and Facilities Management design guides and manuals located at http://www.cfm.va.gov/til/dGuide.asp.

(2) Workspaces where medications are prepared and processed are to be kept clean, orderly, well-lit and free of clutter, distraction and noise.

b. **Staffing Requirements.**

(1) A licensed pharmacist must be on duty during all hours of pharmacy operation.

(2) Pharmacy staffing and hours of operation must be evaluated by the Chief of Pharmacy at least annually to ensure adequate staffing for timely, high quality pharmacy services, taking into consideration facility hours of operation and complexity. Staffing recommendations are available at: https://dvagov.sharepoint.com/sites/VHAClinicalPharmacy/Pages/Homepage.aspx and https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/SitePages/Pharmacy-Operations.aspx. ***NOTE:*** *These are internal VA websites that are not available to the public.*

(3) An Associate Chief, Pharmacy Services position must be included in the Pharmacy Service's organizational chart regardless of facility complexity. This position is necessary due to the diversity of professional pharmacy services, responsibility for the management of a significant percentage of the VA medical facility's operational budget and the need for succession planning. Complexity level 1 and 2 facilities should have a minimum of two Associate Chief, Pharmacy Services positions.

(4) A full-time Administrative Officer or other administrative support position must be provided to the Chief of Pharmacy Services to effectively carry out office requirements. It is recommended that VA medical facility pharmacies have both positions based on the complexity of pharmacy services provided.

(5) A full-time inventory management pharmacist must be designated who is responsible to the oversight of inventory management. This role must not be assigned as collateral duty to responsibilities of another primary role.

(6) There must be adequate pharmacy staff to deliver all services necessary to provide comprehensive, collaborative and patient-centered pharmaceutical care in VA medical facilities. Adequate VA medical facility pharmacy staffing should be ensured based on the appropriate professional, technical and administrative support commensurate with the size and scope of the service. An evaluation of pharmacy staffing should be performed annually and reported to the Executive Leadership Team at the medical facility.

(7) Prescriptions from community providers authorized for community care episodes of care require additional time to ensure compliance with VA's National Formulary, prescribing guidance and community care contract requirements. Facilities must ensure adequate staff are in place to ensure compliance. For all requirements related to Community Care Network outpatient prescriptions, please see Appendix C.

8. MEDICATION SECURITY

a. Access to medications must be limited to those individuals approved by the VA medical facility. The issuance of door keys, security cards or numerical combination access that allow entry into pharmacy service must be restricted by the VA medical facility Chief, Pharmacy Services or designee, to employees who require access. ***NOTE****: Access must also be limited to secure storage area(s) containing expired or soon to be expired drugs*.

b. Keys designated for pharmacy access must be specially mastered keys. Pharmacy keys cannot be mastered to the facility grandmaster and can only be replaced at the request or concurrence of the Chief, Pharmacy Services or designee.

c. Physical security of the pharmacy must be maintained in accordance with current security procedures as defined in VA Handbook 0730, Security and Law Enforcement, dated August 11, 2000.

d. Pharmacy areas, including all doors, must always be secured and access strictly controlled. Based on pharmacy layout and visibility at entrance points, a local process must be established for how non-pharmacy visitors (including housekeeping) will be allowed entrance and accompanied in all pharmacy medication storage areas. ***NOTE****: Controlled substance storage areas must be secured in accordance with VA Handbook 0730, Security and Law Enforcement, dated August 11, 2000.*

e. A monthly review of all pharmacy-controlled access points must be conducted and documented to assure all access is appropriate based on staff assignments and tours. All keys, security cards and codes must be retrieved or removed when a pharmacy employee clears station or leaves pharmacy employment.

f. Prescription medications or medical supplies dispensed by mail must be securely packaged, properly addressed and maintained by the pharmacy service until the courier accepts the packages for delivery. ***NOTE:*** *If a patient reports recurring losses, then alternate delivery processes should be considered with provider notification if clinically appropriate.*

9. MEDICATION STORAGE

All medication storage areas throughout the facility, including wards and clinics, must be approved by the Chief, Pharmacy Services and meet the following requirements:

a. Medications must be maintained per Manufacturer's Special Handling Information (MSHI) recommendations.

b. Temperature must be maintained between 20° to 25°C (Centigrade) (68° to 77°F [Fahrenheit]) in compliance with Office of Construction and Facilities Management design guides and manuals located at http://www.cfm.va.gov/til/dGuide.asp or according to the manufacturer's requirements if different than the above and continuously monitored.

c. Relative humidity (RH) should be maintained between 30 and 60 percent RH in compliance with Office of Construction and Facilities Management design guides and manuals located at http://www.cfm.va.gov/til/dGuide.asp or in accordance with the manufacturer's requirements, if different than the above.

d. If flammable or combustible liquids are being stored in pharmacy, storage cabinets must comply with Occupational Safety & Health Administration (OSHA) requirements. See OSHA requirements at: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10673&p_table=STANDARDS.

e. Medication refrigerators and freezers must follow processes outlined in Appendix F.

f. All approved medication storage areas (including pharmacy storage areas) must be inspected by pharmacy personnel monthly utilizing VA Form 10-0053 Medication Inspection Form for Wards and Clinics. Records of all monthly inspections are maintained with data tracking and trending. ***NOTE:*** *A facility tool may be used if it includes all Form 10-0053 elements.*

g. In Community Based Outpatient Clinics (CBOC) without on-site pharmacy staff, other trained clinic staff can conduct monthly medication storage area reviews. Pharmacy personnel must review the CBOC medication storage area at least once every six months.

h. Sterile multi-dose products (e.g., parenterals, ophthalmics and insulin) must be labeled upon first use with an expiration date that does not exceed 28 days unless a shorter expiration date is recommended by the manufacturer.

i. Non-sterile multi-dose or multi-use topical medications (e.g., bulk oral powders, solutions, ointments) are valid for use until the manufacturer expiration date on the package unless the integrity of the product appears compromised.

j. Corrugated cardboard must be segregated from areas where medications are stored or prepared. ***NOTE****: Work with facility infection control to review segregation plans*.

10. MEDICATION SAFETY

a. The Pharmacy Service, in conjunction with the appropriate interprofessional representatives, must identify medication-related problems and implement measures to improve medication safety. Examples of areas for review include barcode medication administration, medication errors or appropriateness of medication use. For procedures see VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

b. A clinical pharmacist must review all prescriptions and medication orders for the following:

(1) Appropriateness of the drug, dose, frequency, route of administration and instructions for use.

(2) Therapeutic duplications.

(3) Actual or potential allergies and adverse drug reactions.

(4) Actual or potential interactions between medications (including OTCs and herbal supplements), foods, diagnostic agents, supplies or lab interferences.

(5) Therapeutic drug and laboratory monitoring when applicable.

(6) Contraindications.

(7) Applicable criteria for use, clinical practice guidelines or therapeutic indications for use.

(8) Look-alike and sound-alike drug pairs.

(9) Supply items, such as diabetic, enteral nutrition, wound care, incontinence or ostomy supplies are ordered by an authorized individual as outlined in paragraph 13.c.

(10) Special circumstances such as disability or delivery issues.

(11) Any other issues or concerns identified.

c. Allergy and adverse drug reaction (ADR) information must be recorded in the EHR. When the EHR is not available and medications are to be administered or dispensed, documentation must include an allergy assessment. Medications are only to be dispensed if an allergy assessment has been completed. ***NOTE:*** *In emergent situations, when no allergy assessment can be made, the patient's provider and the verifying pharmacist can exercise authority to override this practice on an order-by-order basis. The new EHR supports a documentation of "unable to assess" which may be used to indicate an attempt to document allergy and adverse reaction information.*

d. A CPP is prohibited from verifying their own prescriptions or orders.

e. The VA medical facility must have a local SOP defining dose and interval parameters when the following types of medication orders or prescriptions instructions are used (e.g., as needed, hold orders, automated stop orders, titrating orders, standing orders, taper orders and range orders). Stop dates will be managed at the enterprise level for Cerner implementations.

f. The VA medical facility must identify and implement processes for handling high-alert medications. ***NOTE:*** *Facility listing should align with VHA enterprise-wide listing.*

g. Look-alike and sound-alike drug names require special precautions and require a local list for medications that are stored, dispensed, or administered by a medical facility. Sources for look-alike/sound-alike medication name pairs include the Institute for Safe Medication Practices (https://www.ismp.org/recommendations/confused-drug-names-list) and local patient safety reports. ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

h. The VA medical facility must maintain a "Do Not Use" list of non-approved abbreviations that are prohibited during prescribing. The list must include those required by accreditation agencies. An example is available at https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-do-not-use-list/. ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

i. The VA medical facility must define an interprofessional escalation process with steps beyond prescriber electronic notification to ensure incomplete, illegible or unclear medication orders/prescriptions/consults are clarified in a timely manner. ***NOTE*:** *Pharmacy personnel are prohibited from discontinuing medication orders, prescriptions or consults without approval through the escalation process.*

j. The VA medical facility reviews and approves medication standing orders, order sets and protocols. ***NOTE:*** *Preprinted order sheets are only to be use when prescribing cannot utilize an electronic order entry pathway (e.g. chemotherapy protocol).*

k. Verbal or telephone medication orders in the outpatient setting may only be accepted in an emergency. The pharmacist or registered nurse receiving the verbal or telephone order must immediately read the order back to the provider to verify the accuracy and transcribe the order as soon as possible. ***NOTE:*** *The verbal order must*

be recorded in the EHR. Requirements specific to the inpatient and procedural settings can be found in paragraph 12.g.(5).

l. Remaining portions of partially used bulk inpatient medications (e.g., inhalers, eye drops, creams) that are provided to patients upon discharge must have required outpatient prescription labeling.

m. Risk Evaluation and Mitigation Strategies (REMS) must be fulfilled as required by FDA prior to dispensing or distribution.

n. The VA medical facility must develop and implement interprofessional processes that meet requirements for the safe handling of hazardous drugs including exposure assessment, receipt, storage, distribution, dispensing, administration and disposal. These local processes must consider a VA medical facility's utilization and infrastructure and be in compliance with USP Chapter 800, Hazardous Drugs – Handling in Healthcare Settings, VHA Directive 7702, Industrial Hygiene Exposure Assessment Program dated April 29, 2016 or later.

o. The VA medical facility must have processes in place for pharmaceutical waste disposal in accordance with VA, Federal and State requirements and accreditation standards. Additional pharmaceutical waste guidance is available at http://vaww.hefp.va.gov/resources/pharmaceutical-waste, VHA Directive 7707, VHA Green Environmental Management System (GEMS) & Governing Environmental Policy Statement, dated April 1, 2021 or later, and in VHA Directive 1114, Controlled Substance Patient Prescription Disposal, dated January 11, 2021. ***NOTE:*** *This is an internal VA website that is not available to the public.*

11. PROCUREMENT AND INVENTORY MANAGEMENT

a. **Procurement.**

(1) All procurement staff must complete training, receive ordering officer delegation through the National Acquisition Center (NAC) and follow all requirements in VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020.

(2) The VA pharmaceutical prime vendor (PPV) must be used as the primary source of all contract pharmaceutical purchases. If the drugs are not available from the PPV, then they must be purchased following the VA Acquisition Regulations (VAAR).

(3) "Specialty Distributed" drugs are not available through the prime vendor's normal process. They have an ordering process specific to the manufacturer and are distributed through a specialty distribution company or a third-party distributor. ***NOTE****: The PBM maintains a website with a list of specialty distribution drugs and the process for ordering under the heading "Documents and Lists" at: https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/Special%20Handling%20Drugs/Forms/AllItems.aspx. This is an internal VA website not available to the public.*

(4) There must be a clear separation of duties to minimize the risk of fraud or loss of property. Assignment of duties such as authorizing, approving, recording of all transactions, receiving orders, approving cardholder statements, making payments, certification of funding and reviewing or auditing need to be assigned to separate individuals to the greatest extent possible. ***NOTE****: One person cannot be the cardholder and approving official for the same transaction. Additionally, the individual that places a purchase order cannot receive and check-in the same order*.

(5) All received invoices must be uploaded into the drug accountability or inventory management software.

(6) For VA Fiscal Procurement invoice reconciliation requirements, see Appendix B.

b. **Inventory Management.**

(1) Medication inventory control is an integral part of VA inventory management. VA pharmacy supervisors, inventory managers and purchasing agents must comply with VHA Directive, 1761, VHA Supply Chain Management Operations, dated December 30, 2020, and must implement an inventory management system.

(2) Quarterly VA medical facility PPV inventory turn rate will be provided per VHA Directive 1761 VHA Supply Chain Management Operations and must be reviewed for performance improvement opportunities. Reports can be found at: https://dvagov.sharepoint.com/sites/VHAPBM/AnnualPharmacyWallToWall/VPE_Inventory_documents/Forms/AllItems.aspx. ***NOTE****: End-of-year purchases make pharmaceutical inventories increasingly difficult to manage and are discouraged*. *This is an internal VA website that is not available to the public.*

(3) An annual wall to wall inventory of all pharmacy items must be completed by February 28 of each calendar year and posted to the National Pharmacy Inventory SharePoint (NPIS) site, or current database by March 31.

(4) Units or clinic inventory:

(a) The VistA Automatic Replenishment system is utilized to record medication distribution to units or clinics as the record of inventory accountability for unit/clinic general stock.

(b) Facilities utilizing automated dispensing cabinets and associated inventory tracking software are not required to utilize VistA Automatic Replenishment and may rely on the system's inventory tracking software for inventory accountability.

(c) Unit and clinic medication stock levels are determined by the pharmacy based on utilization and in collaboration with stake holders.

(2) A process must be established for reviewing medications available after hours and adjusting stock levels as needed.

(3) Five non-controlled drugs must be selected from a list developed annually by PBM. These items must be monitored and reported on a quarterly basis, beginning April 1 of each year.

(4) Expired or soon-to-expire medications in each VA medical facility and CMOP must be accounted for as follows:

(a) Drugs designated as return for credit or destruction must be stored in a secure locked area with limited access and separated from normal inventory.

(b) A current inventory must be maintained for non-controlled medications held for return for credit or destruction. At a minimum this list must contain drug name and quantity. ***NOTE****: The contents of opened units or bottles may be estimated.*

(c) If using a reverse distribution vendor, vendor-provided reports must be analyzed to ensure appropriate credits.

(d) Pharmacy inventory must be reconciled with any reverse distributor, tracked and documented.

(e) Destruction of expired or soon-to-be expired non-controlled medications must be witnessed and reconciled with the inventory list.

(5) Disposition of expired or soon-to-be-expired controlled medications must be accounted for as outlined in VHA Directive 1108.01(1), Controlled Substance Management, dated May 1, 2019.

(6) Discrepancies in expired or soon to expire drug inventories must be investigated and addressed.

(7) VA pharmacies must not restock into inventory, or reissue to another patient, any CMOP or locally dispensed prescription medication that has been returned as undeliverable.

12. INPATIENT PHARMACY

a. Medications stocked in patient care areas, including commercially available sterile product solutions, must be labeled with scannable barcodes and inventory quantities are based on utilization. Pharmacy must verify that all barcodes are scannable before distributing.

b. Unit dose bar coded medications are distributed to patient care areas for individual patients for a 24-hour period. Exceptions include Community Living Centers (CLC), long-term care units, Residential Rehabilitation Treatment Programs (RRTP) or domiciliary units which may be issued quantities in excess of a 24-hour supply. ***NOTE:*** *In the instance where unit dose medications may not be available, the Pharmacy will supply the smallest commercial or repackaged size available for patient safety.*

c. In cartless medication systems, unit dose barcoded medications are distributed to patient care areas based on utilization needs.

d. Pharmacy technicians are authorized to deliver and restock barcoded non-controlled unit dose medications to automated dispensing units and medication carts without requiring a second check if all required product checks are completed. ***NOTE:*** *Job specific competencies related to unit dose stocking and replenishment must be part of the technician's performance plan.*

e. Standardized administration and delivery times must be established to ensure the timely administration of medications. Response times for off-schedule dispensing of "STAT", "NOW" and change orders must be established through facility level standard operating procedures.

f. VA medical facility Logistics may stock non-drug containing solutions.

g. **Medication orders.**

(1) Authorized prescribers must enter all orders in the EHR. If EHR is unavailable, the VA medical facility's process for computer down time will be used. The medication order must have the patient's name and identifiers, medication name, dosage, dosage schedule or desired flow rate, duration of therapy, and other information as established by local VA medical facility.

(2) A pharmacist must verify all inpatient medication orders and consider the current diagnosis and indication for each medication.

(3) Local SOP must define the requirements for indication for use on the medication orders.

(4) Medication order reviews may be performed by a pharmacist at a remote location. This review must be completed before the first dose is administered.

(5) All medication orders are reviewed by a licensed clinical pharmacist prior to the administration of the drug, except when required for:

(a) Emergent or urgent need.

(b) Where all processes (i.e., ordering, obtaining and administration) are controlled by a licensed independent practitioner (LIP).

(c) Given as a verbal order during or immediately preceding a procedure, while under the direct supervision of the LIP performing the procedure. The provider must sign the order(s) for medications administered during the procedure within one business day. ***NOTE:*** *In VistA/CPRS, a nurse may enter the medication order in the electronic health record and hold for provider signature the actual medication and dose provided following the conclusion of the case. In Oracle Health, procedures and timeframes differ*

and should follow the Medication Administration Standard Operating Procedure, VHA-ONS-NUR-23-03.

(6) . All VA medical facilities must be compliant with the Joint Commission Medication Management Standard MM.04.01.01. ***NOTE:*** *Refer to VHA Directive 1108.01(1), Controlled Substances Management for local document requirements regarding controlled substance management and accountability.*

(7) End product evaluation and visual testing for all compounded sterile products (CSP) prepared in-house and any CSP procured from an outsourced vendor, for use in-house, must be checked by a clinical pharmacist prior to dispensing the product for patient administration. The end product testing shall include an evaluation for:

(a) Container leaks.

(b) Container integrity.

(c) Solution cloudiness or phase separation.

(d) Particulates in the solution.

(e) Appropriate solution color.

(f) Solution volume.

(g) Identity of the drug and additives (e.g., drugs, diluents, solutions) with the quantity of each additive evidenced by the empty vials or ampoules used. ***NOTE****: This item pertains to those products compounded in-house.*

h. When the onsite pharmacy is not open 24 hours a day and 7 days a week, a pharmacist must be available either on-call or at another location to answer questions or provide access to medications that are not available to non-pharmacy staff. ***NOTE:*** *Medications can be stored in an afterhours cabinet or automated dispensing cabinet.*

i. **Medication Brought into a VA Medical Facility by Patients.**

(1) Patients are discouraged from bringing their medications when admitted to the hospital. If medications are brought in by the patient, the medications should be returned to the patient's caregiver, mailed by patient to their home or securely stored with patient belongings. For disposition of controlled substances brought into to the hospital, see VHA Directive 1114.

(2) In the unlikely event pharmacy service cannot obtain a medication or supply, a prescriber can authorize the use of a patient's own medication. A pharmacist must verify and relabel the medication prior to administration to the patient. Controlled and illicit substances are excluded.

13. OUTPATIENT PHARMACY

a. **Prescriptions.**

(1) VA medical facility authorized prescribers must enter all orders in the EHR. Community Care Network (CCN) prescribers may prescribe electronically, via facsimile or with a hard copy prescription. ***NOTE:*** *For requirements pertaining to CCN prescriptions, please refer to requirements outlined in appendix C.*

(2) Outpatient prescription services must be provided to Veterans in a timely manner. Prescriptions must be ready for pick-up in 30 minutes on average. Facilities must monitor and address extended wait times.

(3) All prescriptions must be verified in the EHR by a pharmacist prior to filling, and all order checks must be addressed. ***NOTE:*** *If a duplicate prescription order check is noted, see Appendix E for the process to cancel or hold prescription at the other VA medical facility.*

(4) Renewed prescriptions must be evaluated by a clinical pharmacist to prevent dispensing if the patient has sufficient supply.

(5) Internal and external written prescriptions must contain the following:

(a) Patient's full name.

(b) Social Security Number (SSN) last four digits or patient's date of birth.

(c) Patient's current address.

(d) Generic name of medication is preferred.

(e) Dosage form.

(f) Strength (in metric).

(g) Quantity.

(h) Directions for use.

(i) Number of refills.

(j) DEA number. (For additional information, see VHA Directive 1108.01(1).)

(6) Non-controlled prescriptions are valid for one year from the date of issue, unless otherwise specified. Controlled substance CIII-V prescriptions are valid for six months from the date of issue, unless otherwise specified. CII prescriptions greater than 14 days from the date of issue should be verified for continued need prior to dispensing.

(7) The VA medical facility may have an SOP outlining extension of fills greater than 12 months in certain circumstances.

(8) On a limited basis, the VA medical facility may fill a patient's outpatient medications prior to the normal dispensing date if a Veteran will be traveling.

(9) Prescriptions must generally be filled for no more than a maximum three-month (90-day) supply of medication. However, exceptions can be made for non-controlled medications and supplies to avoid breaking commercial package size, and for oral contraceptives if requested by the Veteran and their provider.

(10) Prescriptions for low-cost drugs to treat chronic conditions should be dispensed in greater than 30-day supplies if clinically appropriate, is in accordance with the VA medical facility's processes and there is not specific direction from the prescriber to limit supplies. ***NOTE:*** *Prescriptions may be limited to a supply of 30 days or less based on patient safety, patient care needs or facility resources, including, for example, controlled substances (unless specified by VHA Directive 1108.01(1)), research medications or any medications with a restriction specified by the VA National Formulary (VANF).*

(11) Routine prescription refills at the VA medical facility pharmacy window should be limited and mailout prescriptions encouraged.

(12) FDA Medication Guides and patient information associated with outpatient prescriptions must be provided as required by law, regulation, accreditation agencies or VHA policy.

(13) All filled prescriptions must be checked by a clinical pharmacist for accuracy, appropriate labeling (including auxiliary labels) and all necessary printed information prior to dispensing.

(14) Two forms of patient identification are required prior to dispensing prescriptions at the pharmacy window and must adhere to local VA medical facility guidelines for patient identification. ***NOTE****: Pharmacy staff should verify the patient's mailing address listed in the EHR is correct.*

(15) Patient medication counseling, individualized patient education and/or written patient information is provided to patients receiving VA prescriptions as required by law, regulation or accrediting agencies.

(16) Prescribers authorized by their State license and meeting all the requirements for the state in which the prescription will be filled may telephone prescription to a non-VA pharmacy at the Veteran's request. Telephone prescriptions must be documented in the EHR and include pharmacy name, telephone number and medication. The medication must also be documented in the Non-VA medication section.

(17) Authorized prescribers cannot delegate telephone orders to other staff. ***NOTE****: The authorized prescriber may delegate the faxing (or similar electronic means) of written and signed prescriptions to other members of the healthcare team as deemed appropriate at the local facility level.*

(18) The non-VA medication file has been developed and must be used for the purpose of documenting medications obtained outside of VA, including prescription medication, over-the-counter medication, herbals and nutraceuticals. It is particularly important that any medications prescribed by authorized prescribers for outside fill are documented in this file.

(19) The outpatient pharmacy label reprint function must be limited. EHR data must be reviewed at least monthly to evaluate the appropriateness of each reprinted prescription label.

(20) Partial prescriptions are discouraged and should be limited. No partial prescriptions are allowed for controlled substances.

(21) Prescription records must be readily retrievable. Hardcopy prescriptions must be stored in accordance with regulations and VA record management. ***NOTE:*** *This includes documentation utilized during downtimes and then transcribed into the EHR.*

(22) The outpatient pending file must be monitored to ensure timely customer service. When a review indicates that a backlog of more than 25 prescriptions more than 7 calendar days old for 4 consecutive weeks, the following steps must be taken:

(a) Report to the VA medical facility Director the number of unfilled prescriptions, date range, the circumstances causing the backlog, actions to correct the backlog and timeline for resolution. This report is submitted weekly until the matter is resolved. The report and action plan must be provided to the VPE and the Chief Consultant, PBM.

(b) Implement strategies to resolve current and prevent future backlogs to ensure patients do not run out of medications.

b. **Facility Processes for Consolidated Mail Outpatient Pharmacy.**

(1) Prescriptions transmitted to the CMOP must have all required elements of a complete prescription including valid and current patient mailing address.

(2) The CMOP National Web Application function “File a QA Report” is used to communicate concerns, complaints or patient safety incidents to CMOP regarding outpatient prescriptions that have been transmitted to and fulfilled by CMOP. This includes reporting of controlled substances schedule III, IV and V dispensed and mailed from CMOP that are lost in transit or damaged. VA medical facility staff must provide sufficient detail in the QA Report to CMOP regarding each incident.

(3) The VA medical facility pharmacy must immediately contact the local CMOP Patient Safety Manager when the VA medical facility becomes aware of a sentinel event associated with an outpatient order fulfilled by CMOP.

(4) The VA medical facility pharmacy must notify CMOP of prospective inventory changes or inventory requirements for new or existing products at least 5 working days prior to transmitting a prescription order to CMOP.

(5) The VA medical facility pharmacy must install and maintain required software and patches to effectively transmit outpatient prescriptions to CMOP and to receive data from CMOP regarding the fulfillment of prescriptions.

c. **Non-medication Protocols.**

(1) Although medications may only be prescribed by authorized prescribers, non-medication protocols intended for use by non-providers (e.g., registered dieticians, pharmacy technicians and registered nurses) may be utilized in the outpatient setting only if they meet the following criteria:

(a) The protocol addresses a gap in patient care needs (e.g., a registered dietician may be authorized under a VA medical facility policy to order oral nutritional supplementation) ***NOTE****: Medication protocols must only be used in accordance with VHA Directive 1108.13(1) Provision and Use of Nursing Medication Management Protocols in the Outpatient Team-Based Practice Settings dated February 6, 2019*.

(b) The protocol was developed in accordance with the VANF process and national guidelines. VISN or VA medical facility policy must restrict, or exclude, selected medical supply items to assure safe and cost-effective use.

(c) An interprofessional clinical approval process exists for all non-medication protocols that defines elements related to specific use and oversight.

(d) The use of the protocols is agreed upon and approved by the P&T Committee, corresponding Service Chiefs, and the appropriate approving body such as the Medical Executive Committee (MEC) or Clinical Executive Board (CEB).

d. Patient eligibility is determined by the VA medical facility Eligibility Office. Eligibility and or enrollment in special programs is typically annotated in the EHR and used to inform VA medical facility pharmacy prescription dispensing parameters (e.g., incarcerated Veterans cannot receive outpatient prescriptions). ***NOTE****: VHA Directive 1601A.02(1), Registration Eligibility Determination, dated July 6, 2020.*

14. SPECIAL MEDICATION DISPENSING CIRCUMSTANCES

a. **Provision of Medication in Home Health Setting.**

(1) All medications must be prescribed by an authorized prescriber and verified by a pharmacist. ***NOTE****: VA medical facilities may approve protocols for limited medications (e.g., influenza vaccine) to be administered without a provider's order and pharmacist verification.*

(2) VA medical facilities must establish SOPs for transporting medications and supplies to a Veteran's home. Security measures must be reviewed and approved by VA Security and Law Enforcement. The processes must be developed in collaboration with HBPC, MHICM, other home-based or rural programs and include:

(a) Pick up of prescription(s) and supplies from pharmacy.

(b) Chain of custody for all prescriptions, medications and supplies.

(c) Transport in locked containers that do not identify the contents.

(d) Storage of container in vehicle out of plain sight.

(e) Transport under appropriate storage conditions.

(f) Temperature monitoring for all refrigerated items

(g) Personal Protective Equipment (PPE) and a spill kit whenever hazardous drug transportation and administration is to occur in a home health setting

(3) Staff must return unadministered or partially used medications (e.g., partial vial, intravenous solutions) to the VA medical facility by the end of their shift for proper disposition. ***NOTE****: VA medical facility staff will not accept unwanted or unneeded patient specific medications and dispensed prescriptions (including controlled substances) for disposal when visiting the patient.*

b. **Medications for Veterans in Long-Term Care Facilities.**

(1) **Medications for Veterans in Contract Long-Term Care Facilities.**

(a) When the contract specifies that medications and medical supplies are not included in the per diem rate, medications and supplies must be provided by the VA medical facility that authorized the care. ***NOTE****: If an authorized VA provider prescribes the medication, the contract must be examined in conjunction with community care and contracting to determine if the VA medical facility is obligated to provide the medications*.

(b) Prescriptions may be dispensed in bulk if permitted by State regulations and the long-term care facility in which the Veteran resides.

(c) If bulk prescriptions are not permitted, VA must provide medications in unit-dose or packaging compliant with the contract long-term care facility's medication management distribution system.

1. VA will continue to supply bulk prescription medication vials in States that allow repackaging of bulk prescriptions to be compatible with the long-term care facility's medication distribution system. ***NOTE****: VA is responsible for any additional costs incurred by the patient as a result of the repackaging if required by the contract.*

2. If the VA cannot provide packaging compatible with the long-term care facility's medication distribution system, VA must use one of the following options:

a. VA contracts with the primary pharmacy provider used by the long-term care facility to reimburse and allow that pharmacy provider to supply medications in compatible packaging.

b. VA contracts with an alternate pharmacy which can meet the specific medication distribution system or dispensing needs of the facility.

(2) **Medications for Veterans in State Veterans Homes (SVH).** Pursuant to 38 C.F.R. §§ 51.41 and 17.96, VA may furnish a drug or medicine for certain eligible Veterans who are not otherwise eligible for higher per diem under 38 U.S.C. § 1745(a). The drug must be packaged in a form that is mutually acceptable to the SVH and to VA as set forth in a written agreement. ***NOTE****: In accordance with 38 C.F.R. § 51.43(c), VA may furnish a drug or medicine if the drug or medicine is included on VA's National Formulary, unless VA determines a non-Formulary drug or medicine is medically necessary.*

(3) **Medications for Veterans in State Health Care Facilities.** States have a legal duty to provide needed health care to patients in their facilities. In accordance with 38 U.S.C. § 1710(h) as implemented by 38 C.F.R. 17.38(c)(5), VA does not provide medications to patients in these facilities unless a Veteran meets the requirements as per VHA Directive 1601A.02(1), Registration Eligibility Determination, dated July 6, 2020. ***NOTE****: Check with local Eligibility office to determine if medications are provided*.

(4) **Medications for Veterans in Non-Contract Private Long-Term Care Facilities.**

(a) If a community provider prescribes medications for a Veteran in a private long-term care facility and VA is not paying for the care under a contract, VA must provide the medications prescribed if the Veteran meets the eligibility requirements of VHA Directive 1601A.02(1), Registration Eligibility Determination, dated July 6, 2020. ***NOTE:*** *Check with local Eligibility office to determine if Veteran is eligible to receive medications from the VA Medical Facility.*

(b) VA must provide medication prescribed by a VA authorized prescriber for a Veteran in a private long-term care facility not under a VA contract. ***NOTE****: Private long-term care facilities may have their own pharmacies or contracts with private pharmacies who provide medication distribution systems. Veterans may choose to receive medications through the long-term care facility system.*

(c) If the long-term care facility is unable to accept the VA's system of individually packaged medications supplied to them, VA must use one of the following options to ensure the provision of needed medications to Veterans:

1. VA must enter into a contract to reimburse the primary pharmacy provider, contracted by the long-term care facility, to allow for that pharmacy provider to supply medications in the same medication distribution system as all of their other residents.

2. VA must provide for a contracted pharmacy which is able to meet the specific medication distribution system or dispensing needs of the long-term care facility.

c. **Prescriptions for Active Duty or Discharged Military.**

(1) Active duty Service members who are provided VA health care are to be continued on medications prescribed by Department of Defense (DoD) if the VA health care provider identifies no safety or appropriateness concerns. DoD-prescribed medications must be continued regardless of VA Formulary status or prescribing guidelines.

(2) A National Guard or Military Reserve veteran who is receiving VA health care and is activated may receive up to a 3-month supply of medications (with no refills) at the time of deployment.

(3) VA providers are permitted to change medications for discharged service members. However, mental health medications must be continued unless there are safety or appropriateness concerns. See VHA Directive 1108.15, Continuation of Mental Health Medications Initiated by DoD Authorized Providers, dated August 2, 2019 for guidance on changing discharged service members' mental health medications.

d. **Prescriptions for Veterans Outside of the United States.**

(1) VA medical facility pharmacies and CMOPs can only mail prescriptions or medical/surgical supplies within the United States (U.S.) (which include U.S. Territories and possessions, the District of Columbia (DC) and the Commonwealth of Puerto Rico). ***NOTE**: The Federated State of Micronesia, Palau and the Marshall Islands are considered outside the U.S and are covered by the Foreign Medical Program (FMP).*

(2) For eligible Veterans living or traveling abroad, VA offers medical services through the FMP. Through this program, FMP will pay for health care services, medications, and durable medical equipment for service-connected (SC) conditions and conditions associated with and held to be aggravating a SC condition. VA may authorize foreign medical services for any condition if you are participating in the VA Vocational Rehabilitation Program (Title 38, U.S. Code, Chapter 31). ***NOTE**: FMP is administered by the Office of Community Care. For further information, see https://www.va.gov/COMMUNITYCARE/programs/veterans/fmp/index.asp*.

(3) Veterans with SC disabilities who receive outpatient care within the limits of the Manila VA Outpatient Clinic may be provided drugs prescribed by VA as part of that care at the Clinic.

15. TRAINING

There are no formal training requirements associated with this directive.

16. RECORDS MANAGEMENT

a. All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

17. REFERENCES

a. P.L. 104-191.

b. P.L. 105-33.

c. Office of Construction and Facilities Management, Design Guides (PG-18-12).

d. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Vaccine Storage & Handling Toolkit. January 2018. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

e. VA Directive 0730, Security and Law Enforcement, dated August 11, 2000.

f. VA Handbook 5005, Staffing, Part II, Appendix II-G15, dated June 7, 2012.

g. VA Handbook 7002, Logistics Management Procedures, dated January 8, 2020.

h. VHA Directive 1108.01(1), Controlled Substances Management, dated May 1, 2019.

i. VHA Directive 1114(1), Controlled Substance Patient Prescription Disposal, dated January 11, 2021.

q. VHA Directive 1601A.02(4), Eligibility Determination, dated July 6, 2020.

r. VHA Directive 1761, Supply Chain Inventory Management Operations, dated December 30, 2020.

s. VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022.

t. VHA Directive 1108.15, Continuation of Mental Health Medications Initiated by Department of Defense Authorized Providers, dated July 14, 2023.

u. American Society of Health-System Pharmacists. ASHP Guidelines on the Safe Use of Automated Dispensing Devices. Am J Health-Syst Pharm. 2010;67:483-90, available at: https://academic.oup.com/ajhp/article/67/6/483/5130071?login=true.

v. American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role with respect to drug delivery systems and administration devices. American Journal of Hospital Pharmacists (AM J Hosp Pharm) 1993; 50:1724-5, available at: https://www.ashp.org/-/media/assets/policy-

guidelines/docs/statements/pharmacists-role-with-respect-drug-delivery-systems.ashx?la=en&hash=9761C8E2E3898DBBD97CBB8D2E361C0D9B4ACA9C. ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

w. The Joint Commission. Standards FAQ Details. Refrigerator-Design Quality.https://www.jointcommission.org/standards/standard-faqs/ambulatory/environment-of-care-ec/000001250/. ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

x. Hazardous Drugs – Handling in Healthcare Settings (General Information Chapter <800>). The United States Pharmacopeia, 39th rev., and the National Formulary, 34th ed. Rockville, MD: United States Pharmacopeia Convention, 2016.

PHARMACY EDUCATION AND TRAINING

a. EDUCATION AND TRAINING PROGRAMS

(1) All pharmacy trainees are under the direction and supervision of the Chief, Pharmacy Service or designee and all post-graduate trainees must be United States citizens and graduates of an Accreditation Council for Pharmacy Education (ACPE) accredited College of Pharmacy.

(2) All pharmacy residency programs are accredited through American Society of Health-System Pharmacists (ASHP). ASHP is a sole source for accreditation and performs site visits for accreditation. There are accreditation fees for these services and these fees are the responsibility of the Department of Veterans Affairs (VA) medical facility Director.

(3) ASHP accredited residency programs are expected to follow the ASHP standards for the programs and include following requirements as specified by ASHP for Pharmacy Graduate Year (PGY)1 standards or specialty PGY2 standards.

(a) A pharmacy resident must achieve licensure within 120 days of the start date of the residency, in accordance with the applicable ASHP residency standards. Exceptions to this will be considered on a case-by-case basis by the Pharmacy Benefits Management (PBM) National Director of Residency Programs and Education. ***NOTE:*** *The ASHP Residency Standards can be found at: https://www.ashp.org/Professional-Development/Residency-Information/Residency-Program-Resources/Residency-Accreditation/Accreditation-Standards-for-PGY1-Pharmacy-Residencies?loginreturnUrl=SSOCheckOnly. This linked document is outside of VA control and may or may not conform to Section 508 of the Americans with Disabilities Act.*

(b) A resident may be in a First Post-Graduate Year (PGY1) or Second Post-Graduate Year (PGY2) Pharmacy Residency Program that requires successfully completing the goals and objectives. Programs must be a minimum of 52 weeks of full-time practice (2,080 hours) to receive a certificate of completion. In certain circumstances, a pharmacy resident can be concurrently enrolled in an academic program (e.g., Master of Science in Pharmacy Administration and PGY2 in Health Systems Pharmacy Administration and Leadership).

(c) A resident position is specifically designated as a training position and cannot be utilized to supplement staffing vacancies or shortages.

(d) Residents and Fellows do not contribute to the department's Full Time Equivalent Employment (FTEE) ceiling.

(4) Residents may hold a dual appointment for professional duties identified by licensure. PGY1 residents must be assessed and authorized by the Residency Program

Director(s) (RPD) to confirm they can manage their time effectively for both the residency and the dual appointment. PGY2 residents may hold a dual appointment for professional duties identified by licensure and skills obtained through the PGY1 residency. The RPD is responsible for quarterly assessments of resident well-being during the residency and dual appointments to ensure the resident is on schedule to successfully complete the residency.

(5) An Residency Program Director (RPD) must be a clinical pharmacist who has completed an ASHP-accredited residency and have a minimum of three years of pharmacy practice experience; or have completed an ASHP-accredited PGY1 and PGY2 residencies with one or more year of pharmacy practice experience; or without completion of an ASHP-accredited residency, have five or more years of pharmacy practice experience with demonstrated mastery of the knowledge, skills, attitudes and abilities expected of one who has completed a residency. Approval through ASHP is required to be an RPD. RPDs are responsible for tracking the duty hours of trainees. See ASHP Guidance Document at: https://www.ashp.org/-/media/assets/professional-development/residencies/docs/duty-hour-requirements.ashx. ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

(6) All RPDs must have sufficient administrative time allocated to ensure that program development, preceptor development and accreditation processes are fully met.

(7) Preceptors must be clinical pharmacists who have completed an ASHP-accredited PGY1 residency followed by a minimum of one year of pharmacy practice experience; or have completed an ASHP-accredited PGY1 residency followed by an ASHP-accredited PGY2 residency and a minimum of 6 months of pharmacy practice experience; or without completion of an ASHP-accredited residency, have 3 or more years of pharmacy experience. Non-pharmacists may be preceptors in limited circumstances as defined in the ASHP Pharmacy Residency Standards and when a pharmacist preceptor works closely with the non-pharmacist preceptor. https://www.ashp.org/-/media/assets/professional-development/residencies/docs/examples/ASHP-Accreditation-Standard-for-Postgraduate-Residency-Programs-effective-July-2023.pdf ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

(8) Continuing professional development can occur through other educational programs or non-traditional residency training programs to ensure competency. Staff educational needs are to be identified through administration of the National Pharmacy Workforce Assessment. Utilization of in-house training should be encouraged (e.g., CPPO and academic detailing webinars, PBM Clinical Informatics and PBM-EdAC Certificate Programs, VA-ECHO).

(9) Pharmacy Fellowship programs are intended to prepare the Fellow for a position as an independent researcher after graduation. VA Pharmacy Fellowship positions must be accredited by the American College of Clinical Pharmacy (ACCP). ***NOTE**: A fellowship is typically a 2-year program*.

(a) The Pharmacy Fellow must be a clinical pharmacist or a pharmacy graduate of a school or college of pharmacy that is accredited by ACPE. The fellow must be a United States Citizen and eligible for licensure, to receive postgraduate training at a VA medical facility, with the primary objective of doing research, which may or may not be part of an advanced academic degree program.

(b) A fellow position is specifically designated as a training position and cannot be utilized to supplement staffing vacancies or shortages.

b. **STUDENT PROGRAMS**

(1) Students may be hired through the Pathways Program, which is outlined in VA Handbook 5005, Staffing, dated April 15, 2002.

(2) Coverage. This applies to appointments of students and recent graduates in the title 5 excepted service using the Pathways Programs, Schedule D hiring authority. Appointing authorities for the Pathways Programs are found in 5 C.F.R. § 213.3402 and part 362. This section replaces Human Resources Management Letter 05-13-01, Implementing the Title 5 Excepted Service Pathways Programs in VA dated January 3, 2013. The Pathways Programs regulations replace the former Student Career Experience Program (SCEP) and Student Temporary Employment Program (STEP) formerly covered under 5 C.F.R. § 213.3202 and PMF program formerly covered in 5 C.F.R. § 213.3102(ii) and (jj) and 5 C.F.R. part 362.

c. **PLANNING AND IMPLEMENTATION**

The design of the pharmacy training programs should strive for continuous quality improvement and must be consistent with the overall goals and objectives of relevant oversight bodies such as ASHP, OAA and the Pharmacy Residency Program Office when applicable. An interprofessional approach to sponsoring, planning and implementing educational activities is encouraged, and efforts to coordinate with VA staff or professional organization resources need to be made to support education programs whenever feasible and appropriate.

d. **FUNDING**

(1) Approved VA accredited Pharmacy Residency and Fellowship Programs are provided funding support by Office of Academic Affairs (OAA). ASHP Health-Systems Administration and Leadership residencies may be funded locally through an OAA waiver system; consideration for the waiver process may be discussed through the Pharmacy Residency Program Office before a formal request is sent to OAA for a waiver.

(2) All other pharmacy student trainees are appointed on a without compensation (WOC) basis.

e. **PROFESSIONAL AND SCIENTIFIC LITERATURE**

(1) Information is central to the practice of modern pharmacy. Pharmacy is a profession where clinical pharmacists apply clinical drug information that directly impacts patient care. Pharmacy has evolved into a clinical knowledge-based profession where the clinical pharmacist interprets and uses drug data aimed at the optimal utilization of drugs in patients. Pharmacy Service gathers and maintains current information on drug products, pharmaceutical techniques, clinical drug therapeutics, adverse events and other developments in the use of drugs.

(2) The pharmacy service must maintain sufficient resources to complete the patient care, education and research missions of the pharmacy program.

PROCUREMENT, INVENTORY AND FISCAL PROCESSES

Pharmacy Procurement and Contracting Activities:

1. Procurement and contracting activities involve the purchase of drugs, supplies (both drug related and operational), automation and services and must comply with VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020.

2. There must be a clear separation of duties to minimize the risk of fraud or loss of property. Assignment of duties, such as: authorizing, approving and recording transactions; receiving assets; approving cardholder statements; making payments; certification of funding; and reviewing or auditing, need to be assigned to separate individuals to the greatest extent possible. ***NOTE:*** *For clarification, one person cannot be the cardholder and approving official for the same transaction. An ordering official cannot be a contracting officer representative.*

3. Pharmaceutical orders are reconciled with items delivered, noting any discrepancies.

4. Invoice or packing slip are reviewed for signature and date. ***NOTE:*** *There must be evidence of receipt of all goods ordered via VA Form 1358, Obligation or Change in Obligation; purchase cards; VA Form 2237, Request, Turn-In and Receipt for Property or Services; or similar to justify payment. VA Handbook 7002, Logistics Management Procedures, dated January 8, 2020, Part 4, requires designated receiving individuals to accept and inspect all goods ordered and received.*

5. Purchase card orders received by the warehouse must be reviewed to validate that they have signatures on the receiving report from warehouse staff or by the reviewing pharmacy personnel. ***NOTE:*** *Purchase card orders received directly in pharmacy must be signed (invoice/packing slip) by the responsible pharmacy staff member. See VA Handbook 7002, which requires designated receiving individuals to certify receipt, inspection and acceptance of goods ordered and received.*

6. The Fiscal B09 report is reviewed and reconciled with VA Form 1358s to ensure pharmacy is making correct payments for purchases received and with documented evidence (signature and date of review) it has been completed. ***NOTE:*** *The Fiscal B09 report is generated weekly from the Financial Services Center, Austin, Texas and is a summary of several invoices. Refer to VA Financial Policy XVI, Chapter 1.*

7. Monthly documentation is submitted to Fiscal Service stating the VA Form 1358s and BO9 reports were reconciled and noting any unresolved discrepancies.

8. Fiscal Service must notate fiscal service reconciliation on the submitted monthly documentation and return to Pharmacy Service.

9. Financial Management and Accounting Systems Alert Volume 2013, issue 001 contains SOPs for BO9 reconciliation process and can be found at:

https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/SitePages/Pharmacy-Operations.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

COMMUNITY CARE NETWORK OUTPATIENT PRESCRIPTIONS

1. The Department of Veterans Affairs (VA) Pharmacy is authorized to fill prescriptions from authorized community providers in compliance with VA's Formulary Management Process. Community providers who are unwilling to comply with VA's Formulary Process should be reported to local or Veterans Integrated Services Network (VISN) Office of Community Care staff as per Veterans Health Administration (VHA) Directive 1108.08(1), VHA Formulary Management Process, dated November 2, 2016.

a. VA pharmacy should not accept verbal or telephoned outpatient prescriptions from community providers or "transfer" prescriptions from non-VA pharmacies.

b. VA pharmacy must ensure Community Care Network (CCN) Veteran patient's allergy information is obtained and documented in the VA electronic health record.

c. VA pharmacy has the responsibility to determine the Service Connection (SC) or Special Authority (SA) co-payment status for community care prescriptions.

d. VA providers must not be asked or be required to re-write prescriptions written by authorized community providers. There is no situation where VA prescribers are required to re-write community care prescriptions against their clinical judgement per VHA Directive 1310, Medical Management of Enrolled Veterans Receiving Self-Directed Care from External Health Care Providers, dated October 4, 2021.

e. Electronic prescribing is the preferred method to receive prescriptions at a VA pharmacy, including controlled substances. Prescriptions may also be presented in person, mailed, or faxed.

f. All controlled substance prescriptions should be filled in compliance with VHA Directive 1108.01(2), Controlled Substances Management. Additional state limitations may also apply based on local policy. The prescribing community care provider is responsible for querying state PDMP per their own state licensure requirements.

2. For additional details please refer to the Community Care Network Pharmacy Frequently Asked Questions at: Community Care Network Pharmacy (sharepoint.com) or https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/Other%20Documents%20and%20Resources/CCN%20Pharmacy%20FAQ%20FINAL%20June%202022.pdf ***NOTE:*** *This is an internal VA website that is not available to the public.*

UNIT DOSE OR OUTPATIENT REPACKAGING

1. Medications purchased in bulk containers may need to be repackaged into unit dose packaging for distribution or common outpatient quantities prior to dispensing.

2. Repackaging may alter the characteristics of drug products such as affect stability, safety and efficacy. The package insert should be consulted prior to repackaging.

3. Each unit of repackaged drug must be properly labeled. The following information must appear on each label:

a. Generic drug name and formulation.

b. Strength or concentration – in metric units (e.g., mg, mcg, ml).

c. Lot number.

d. Expiration date.

e. Barcode for unit dose use.

f. Quantity – for outpatient.

4. All repackaged drugs must be checked by a pharmacist prior to being placed in stock for dispensing. A pharmacist must complete the following:

a. Correct drug is being packaged.

b. The label is reviewed for correct content, format, spelling and legibility.

c. The entries on the repacking record are accurate.

d. The amount of drug to be packaged is not excessive based on expiration date.

5. Properly labeled repackaged or starter supplies of urgent outpatient medications (e.g., antibiotics, pain medications, etc.) may be stored in designated areas such as the Emergency Department if dispensed directly to the patient by a licensed independent practitioner . ***NOTE****: Patient label must include all elements of an outpatient prescription prior to dispensing*

PRESCRIPTION CANCEL PROCESS FOR DUPLICATE PRESCRIPTIONS AT OTHER VA MEDICAL FACILITIES

1. To cancel a prescription, use the "Cancel Prescription POC, Pharmacy" page of the Department of Veterans Affairs (VA) Pharmacy Benefits Management (PBM) Pharmacy Directory and select the "Cancel Prescription POC, Pharmacy" view or filter the "Position Title" column by "Cancel Prescription POC, Pharmacy". ***NOTE:*** *This directory is located at:* https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Directory/Lists/Directory/CancelPrescriptionPOC.aspx. *This is an internal VA website that is not available to the public.*

2. Locate the VA medical facility that has the active duplicate prescription.

3. Click on the email address field to generate an email; ensuring that pharmacy staff adheres to all electronic privacy requirements. Do not email to any other email group that is not listed in the PBM Pharmacy Directory as a "Cancel Prescription Contact, POC".

4. Enter the following information into the email:

a. Subject: Cancel/Hold Prescription.

b. Body: A patient previously assigned to the facility is now receiving medications from [enter the prescribing facility name].

c. Reviewing the pharmacy duplicate remote medication entered on ___ [insert date] ___ for specific information.

d. Cancel the following prescription numbers ___[list prescription numbers]__.
NOTE: *Once the email is sent, it should be received by the individual(s) identified at the previous facility.*

5. The "Cancel Prescription POC, Pharmacy" at the receiving facility is to review the progress note entered by the prescribing facility and take the appropriate actions. In general, it is recommended that the receiving facility cancel the prescription and enter a progress note.

6. A local Department of Veterans Affairs medical facility standard operating procedure may be created for holding or taking other actions on the duplicate prescriptions if canceling the prescriptions would contradict existing procedures that are implemented for patient safety reasons.

MEDICATION REFRIGERATOR AND FREEZER PROGRAM MANAGEMENT

1. All Department of Veterans Affairs (VA) medical facilities must have a local medical center policy on medication and vaccine refrigerator and freezer program management that contains all required elements outlined in the local policy template developed by PBM and contains the principles and concepts explained within this appendix. ***NOTE:*** *Guidance on drafting the medical center policy is available at* https://dvagov.sharepoint.com/:w:/r/sites/VHAClinicalPharmacy/CPPO Documents/Medical Center Policy Template for Refrigerators Freezers 6_17_26.docx?d=w28166d04d91a46468bee0e808fc9e53f&csf=1&web=1&e=7dRqEy&xsdata=MDV8MDJ8fDFlZjNlNmE5MzE5YjRkNWI2MDRmMDhkZjE3ZjQ4NjJjfGU5NWYxYjIzYWJhZjQ1ZWU4MjFkYjdhYjI1MWFiM2JmfDB8MHw2MzkyNTYwMTExMjkwMTIwMTh8VW5rbm93bnxUV0ZwYkdac2IzZDhleUpGYlhCMGVVMWhjR2tpT25SeWRXVXNJbFlpT2lJd0xqQXVNREF3TUNJc0lsQWlPaUpYYVc0ek1pSXNJa0ZPSWpvaVRXRnBiQ0lzSWxkVUlqb3lmUT09fDB8fHw%3d&sdata=bzRFYUlhYzkwUnp6UXpCK1pvbnMvb2pvUkF1c05Mc2hPM1MwNm56aENMTT0%3d*. Guidance on drafting the standard operating procedure is available at* https://dvagov.sharepoint.com/:w:/r/sites/VHAClinicalPharmacy/CPPO Documents/Medical Center SOP Template for Storage of Vaccines and Medications in Pharmaceutical Grade Refrigerators and Freezers 10_19_2022.docx?d=w9d323a3dbf4f470b93d7f20099aebfdc&csf=1&web=1&e=7FP56D&xsdata=MDV8MDJ8fDFlZjNlNmE5MzE5YjRkNWI2MDRmMDhkZjE3ZjQ4NjJjfGU5NWYxYjIzYWJhZjQ1ZWU4MjFkYjdhYjI1MWFiM2JmfDB8MHw2MzkyNTYwMTExMjkwMjUxOTB8VW5rbm93bnxUV0ZwYkdac2IzZDhleUpGYlhCMGVVMWhjR2tpT25SeWRXVXNJbFlpT2lJd0xqQXVNREF3TUNJc0lsQWlPaUpYYVc0ek1pSXNJa0ZPSWpvaVRXRnBiQ0lzSWxkVUlqb3lmUT09fDB8fHw%3d&sdata=SlhXT1RwcVd3UDREQzA5Qm9Xa3NhZnBqZkpUNXFPbVRaYlRnVUhlYTJRTT0%3d*. These are internal websites that are not available to the public.*

2. Vaccines and medications can lose their potency when exposed to excessive heat, cold or light. While exposure to any inappropriate conditions can affect potency of refrigerated vaccines, a single exposure to freezing temperatures (0 degrees Celsius or colder) may destroy some vaccines.

3. Veterans Health Administration (VHA) must monitor the temperatures of medication refrigerators and freezers to meet the U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC) recommendations. Medications and vaccines are not to be stored in dormitory-style, bar-style, combined refrigerator or freezer units under any circumstance. Pharmaceutical grade, purpose-built refrigerators provide consistent temperature control to avoid damaging fragile medications. ***NOTE:*** *For more information on proper vaccine storage and handling, please see the CDC website at: https://www.cdc.gov/vaccines/hcp/admin/storage/index.html.*

4. ADDITIONAL RESOURCES

a. **Buffered Temperature Probe.** A buffered temperature probe is designed to prevent false readings by protecting the thermometer from sudden changes in temperature that can occur when opening a refrigerator door. A probe is considered buffered by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads) or a solid block of material (e.g., Teflon®, aluminum).

b. **Calibration.** Calibration is professional verification with written certification of the accuracy of a temperature monitoring device.

c. **Cascade Alarm (Escalation Process).** Cascade Alarm, or escalation process, is the process that occurs when a temperature excursion or power loss alert is received by the first response group (or individual), if no action is taken, a secondary response group will be contacted, if no action is taken, the cascade will continue until there is corrective action.

d. **Digital Data Logger.** Digital data logger (DDL) is an electronic device that records data digitally over time either with a built-in or external instrument or sensor and for the purposes of this directive, will include details on how long a unit has been operating outside the recommended temperature range. The data must be maintained for three years.

e. **Dormitory-style or Bar-style Storage Unit.** A dormitory-style storage unit is a combination refrigerator or freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

f. **Essential Electrical System.** The Essential Electrical System (EES) as defined in National Fire Protection Association (NFPA) 99, Health Care Facilities Code is comprised of alternate sources of power and all connected distribution systems and ancillary equipment. The system is designed to ensure continuity of electrical power to designated areas and functions of a health care facility during disruption of normal power sources, and to minimize disruption within the internal wiring system.

g. **Pharmaceutical Grade Purpose-built Refrigerator or Freezer.** A pharmaceutical grade purpose-built refrigerator or freezer is designed specifically for storage of drugs and biologics. These often have microprocessor-based temperature control with a digital temperature sensor and fan-forced air circulation or multiple vents that promote uniform temperature. There are large or compact units available.

h. **Temperature Excursion.** Temperature excursion is any temperature reading that is outside the recommended temperature storage range for medications and vaccine storage as defined by the manufacturer.

i. **Temperature Monitoring System.** Temperature monitoring system is a system that provides continuous monitoring and alarm/alert notification of defined temperature excursions.